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K002740

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems.

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	August 31, 2000
Contact Person:	Kim P. Kelly Senior Regulatory & Clinical Affairs Specialist
Proprietary Name:	Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems
Common Name:	Polyethylene Tibial Articular Inserts; All Polyethylene Tibial Components; & Polyethylene Patellas
Classification Name and Reference:	21 CFR 888.3560 Knee joint patello femorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II
Device Product Code and Panel Code:	Orthopedics/87/JWH

I. DEVICE INFORMATION

A. INTENDED USE

The Profix and Genesis II Total Knee Systems are indicated for patients with:

1. Rheumatoid arthritis
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. The constrained knee system is designed for use in patients in primary and revision surgeries, where the posterior cruciate ligament and one or both of the

collateral ligaments (i.e. medial collateral and/or lateral collateral ligaments) are absent or incompetent.

The components subject of this notification are to be used with the Genesis II and Profix Total Knee systems, both of which are indicated for use only with cement and which are single use devices.

B. DEVICE DESCRIPTION

The intended use, base material, dovetail locking mechanisms, and design features of the Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems are the same as the subject identical predicate counterparts fabricated from conventional non cross-linked UHMWPE. The modification to the device subject of this premarket notification is the cross-linking of the UHMWPE by a proprietary process. This results in a highly crosslinked material with increased wear performance properties. Tibial inserts will be available in cruciate retaining, posterior stabilized, constrained, and dished/conforming design options. Additionally, an all polyethylene tibial component (cruciate retaining & posterior stabilized options) will be available in the cross-linked material. Patellar components will be made in the following configurations: biconvex, revision biconvex, resurfacing, Flex-Lok peg, inset, and onset designs.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The overall design and function of the cross-linked components have not been changed over that of their identical counterparts manufactured from conventional UHMWPE. Therefore, with the exception to the modification of the manufacturing process to cross-link the material, the devices subject of this submission are substantially equivalent to the predicate counterparts filed within the following premarket notifications:

A) Profix Knee System (K933958)

B) Profix Conforming Plus Tibial Insert (K946236)

C) Profix Posterior Stabilized Knee System (K954909)

D) Profix Posterior Stabilized Plus Tibial Insert (K963255)

E) Genesis II Cruciate Retaining, Posterior Stabilized and Dished Knee System (K951987)

F) Genesis II Revision System & Porous Tibial Base (K953274)

G) Genesis II Constrained Knee System (K962137)

Crosslinked polyethylene has also been cleared for market for knee applications under the following premarket notifications:

i) Howmedica Corporation's Duration II Tibial Inserts: Gas Plasma Sterilization (K980632)

ii) Howmedica Corporation's Duration II Duracon Tibial Inserts (K980925)

iii) DePuy, Inc.'s AMK and Coordinate Ultra cross-linked polyethylene tibial insets and trays (K982585)

Although, the processing used by Smith & Nephew, Inc. to cross-link the material is not identical to that used in the above stated predicate competitive products, any differences that may exist do not significantly affect the safety and effectiveness of the components.

D. WEAR CLAIMS

The following marketing claims will be made for the Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems:

1. No free radicals detectable when analyzed by Electron Spin Resonance (ESR) (The detection limit is approximately 1×10^{13} spins/gram).
2. No increase in oxidation level over conventional, ETO sterilized UHMWPE after 21 days of accelerated aging at 70°C as measured by Fourier Transform Infrared (FTIR).
3. 95% reduction in gravimetric wear rate versus the identical predicate counterpart fabricated from conventional UHMWPE. Testing was performed in a multiaxial knee joint simulator for a minimum of 5 million cycles per individual test using Size 5 CoCr femoral components as an articulating counterface, size 5 cruciate retaining tibial inserts, and Hyclone bovine calf serum as a lubricant.
4. No delamination was detected during *in vitro* wear testing as analyzed by optical and scanning electron microscopy. Testing was performed on a reciprocating pin-on-disc configuration for a minimum of 3 million cycles using 9 mm diameter cast CoCr pins as an articulating counterface, 35 mm diameter UHMWPE discs, and Hyclone bovine calf serum as a lubricant. Results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

E. SUMMARY OF TECHNOLOGICAL COMPARISON

The intended use, base resin material (prior to crosslinking), type of interface, and design features of the Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems are substantially equivalent to their predicate component counterparts. The raw material used in manufacturing both the subject and predicate devices conforms to ASTM F-648. The modification to the manufacturing process of this polyethylene results in a higher cross-linked polyethylene. The safety and effectiveness of this cross-linked polyethylene in knee applications, as well as the proposed wear claims, are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Abbreviated Premarket Notification. Such information was generated per data requirements outlined in the *Draft Guidance Document for Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-constrained Total Knee Prostheses* dated April 1993 and *Guidance Document for Data*

Requirements For Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used In Bearing Surfaces For Orthopedic Devices, dated September 7, 1997.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2000

Ms. Kim P. Kelly
Senior Regulatory & Clinical Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K002740
Trade Name: Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems
Regulatory Class: II
Product Code: JWH
Dated: August 31, 2000
Received: September 1, 2000

Dear Ms. Kelly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002740

Device Name: ***Tibial & Patellar Components for the Profix & Genesis II Total Knee Systems***

Indications for Use:

The Profix and Genesis II Total Knee Systems are indicated for patients with:

1. Rheumatoid arthritis
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Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002740